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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/052,855	03/31/1998	PATRICIA A. BILLING-MEDEL	6064.US.P1	9597

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1642	45

DATE MAILED: 05/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/052,855	Billings-Medel et al
Examiner	**Art Unit**
Karen Canella	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3 months* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 17-24, 26-29, 31-34, 36, 37, and 44-58* is/are pending in the application.

4a) Of the above, claim(s) *1-9, 17-24, 26-29, 31-34, 36, and 37* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *44-58* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 6, 2003 has been entered.

2. Claims 1-9, 17-24, 26-29, 31-34, 36, 37 and 44-58 are pending. Claims 1-9, 17-24, 26-29, 31-34, 36 and 37 remain withdrawn from consideration. Claims 44-58 are under consideration.

3. The rejection of claims 44-58 under 35 U.S.C. 101, because the claimed invention is not supported by either a credible, specific and substantial utility, or a well-established utility is withdrawn after review and reconsideration in light of applicant's arguments.

4. The rejection of claims 44-58 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn after review and reconsideration in light of applicant's arguments.

New Grounds of Rejection

5. Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The property of encoding at least one epitope is inherent in the polynucleotides of claim 46, thus claim 49, directed to that inherent property fails to further limit claim 46.

6. Claim 53 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 51. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the limitation "comprising a polynucleotide encoding at least one epitope" is inherent in the polynucleotides of claim 50, and is therefore inherent within the cell of claim 51.

7. Claims 50, 51, 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 51 and 53 read on a cell within a human and claim 50 reads on a vector within a human. Amendment of the claims to recite "An isolated recombinant expression system" and "An isolated cell" would overcome this rejection.

8. Claims 46-51, 53, 56, 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The instant claims recite "degenerate coding sequences thereof" without reference to a protein sequence which is being encoded, as SEQ ID NO:1-9, 12 and 13 are all polynucleotide sequences.

9. Claim 52 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a polypeptide comprising expressing the polynucleotides encoding SEQ ID NO:24-28, does not reasonably provide enablement for a method of producing a polypeptide comprising expressing the complete complement of the polynucleotides encoding SEQ ID NO:24-28. The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. .

Claim 52 is drawn in part to a method for producing a polypeptide comprising incubating host cells that have been transfected with a polynucleotide sequence encoding an amino acid sequence selected from the group consisting of the complete complements of SEQ ID NO:24-28.

The specification teaches that the polypeptide of SEQ ID NO:24 is expressed from SEQ ID NO:13. If the complete complement of SEQ ID NO:13 were substituted for SEQ ID NO:13, the resulting transcribed protein would not be structurally or functionally related to SEQ ID NO:24. The specification teaches that SEQ ID NO:25-28 are fragment of SEQ ID NO:24 that were used to raise antibodies, If the complete complements of the poynucleotides encoding SEQ ID NO:25-28 were substituted in an expression vector, the amino acid sequence produced would not generate antibodies which bound to the same sequences as the antibodies which bound to SEQ ID NO:25-28. It is reasonable to assume that these polypeptides would not be representative of the polypeptides associated with colon cancer as taught in the instant specification. Accordingly, the specification is not enabling for how to use the proteins produced by a method which comprises the recombinant expression of the complements of the polynucleotides encoding SEQ ID NO:24-28. One of skill in the art would be subject to undue experimentation in order to use all the proteins of the broadly claimed method.

10. Claims 44-55, 57, 58 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 44-51, 53 and 57 are drawn to polynucleotide sequences comprising the sequence of SEQ ID NO:1-9. The specification identifies said sequences as partial EST sequences (page 56, lines 1-10). The specification does not address whether the partial sequences comprise

intron/exon splice junctions. When given the broadest reasonable interpretation, the claims can be interpreted as reading on genomic sequences, including any full length gene which comprises each of the sequence. Thus, each EST sequence represents a genus of polynucleotides.

The disclosure of a single species of a genus may provide adequate written description of the genus which the species disclosed is representative of the genus. The present claims encompass full length genes, cosmids and chromosomes comprising said genes. Eukaryotic chromosomes and genes are expected to comprise regulatory regions and untranslated intron regions. These regions are not disclosed by the specification. There is substantial variability among the species of polynucleotides encompassed by the genuses because SEQ ID NO:1-9 represent only a fragment of any full length gene or chromosome. Functional attributes such as coding capacity cannot be relied upon to distinguish partial sequence from complete genes and chromosomes because complete genes and chromosomes also would encode the sequence which was deduced from the analysis of the combined partial sequences (SEQ ID NO:24). Amendment of the claims to polynucleotide consisting of SEQ ID NO:1-9 would overcome this rejection.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
>
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent,; or
>
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 44, 46-54, 57 and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Yu et al (U.S. 5,733,748).

Claim 44 is drawn in part to a test kit for detecting a polynucleotide in a test sample comprising a container containing at least one polynucleotide having the sequence of SEQ ID NO:7 and 8 and the complete complements thereof. Claim 46 is drawn in part to a purified polynucleotide having a sequence of SEQ ID NO:7 and 8, and the complete complements thereof. Claim 47 embodies the polynucleotide of claim 46 wherein said polynucleotide is produced by recombinant techniques. Claim 48 embodies the polynucleotide of claim 46 wherein said polynucleotide is produced by synthetic techniques. Claim 49 embodies the polynucleotide of claim 46 wherein said polynucleotide comprises a sequence encoding at least one epitope. Claim 50 is drawn in part to a recombinant expression system comprising a nucleic acid that includes an open reading frame operable linked to a control sequence compatible with a desired host, wherein said nucleic acid sequence comprises a polynucleotide having a sequence of SEQ ID NO:7 and 8, and the complete complement thereof. Claim 51 is drawn to a cell transfected with the expression system of claim 50. Claim 53 is drawn to a cell transfected with a nucleic acid sequence, said nucleic acid sequence comprising a polynucleotide encoding at least one epitope, the polynucleotide having a sequence selected from the group consisting of SEQ ID NO:7 and 8 and the complete complements thereof. Claim 54 is drawn in part to a purified polynucleotide which code for a polypeptide having a sequence selected from the group consisting of SEQ ID NO:27 and 28. Claim 57 is drawn in part to a purified polynucleotide having a DNA sequence selected from the group consisting of SEQ ID NO:7 and 8. Claim 58 is drawn in part to a purified polynucleotide comprising DNA encoding a sequence selected from the group consisting of SEQ ID NO:27 and 28.

Claim 52 is drawn in part to a method of producing a polypeptide comprising at least one epitope said method comprising incubating host cells that have first been transfected with an expression vector containing a polynucleotide sequence encoding a polypeptide having an amino acid sequence selected from the group consisting of SEQ ID NO:27 and 28.

Yu et al disclose Sequence 6 which comprises the instant SE ID NO:7 at nucleotides 10-237 and the instant SEQ ID NO:8 at nucleotides 144-394. Yu et al disclose expression vectors comprising Sequence 6 which operable link the disclosed sequence to a operable promotor, host cells comprising said expression vectors and method of producing recombinant proteins (column 12, line 16 to column 15, line 7). Yu et al disclose that said polynucleotides may be synthetic or recombinant and include both the coding and the anti-sense strand (column 4, lines 62-67), thus fulfilling the specific embodiments of a sequence "having" SEQ ID NO:7 or SEQ ID NO:8 and the complete complements thereof. It is noted that the intended use of the kit in claim 44 does not provide patentable wight to the product of the kit. Yu et al disclose a kit comprising a container filled with one or more ingredients of the invention for human administration (column 16, lines 60-63). Yu et al disclose the antisense constructs of Sequence 6 as a pharmaceutical composition. Therefore, Yu et al disclose a kit comprising the complete complement of Sequence 6, which would anticipate a kit comprising a polynucleotide having a sequence selected from the group consisting of the complete complement of SEQ ID NO:7 and SEQ ID NO:8. Yu et al also disclose Sequence 7 which comprises the sequence of SEQ ID NO:27 at residues 45-81 and SEQ ID NO:28 at residues 90-129. Yu et al disclose a process of producing Sequence 7 comprising culturing recombinant procaryotic or eukaryotic host cells in culture under conditions promoting expression of said protein and subsequently recovering said protein (column 2, lines 58-64).

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 44-55, 57 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yu et al (U.S. 5,733,748) in view of Feuerstein et al (U.S. 5,994,529) and Quattrocchi (WO 95/15493).

Claim 45 is drawn to the kit of claim 44 further comprising tools useful fr the collection of the test sample the tolls selected from the group consisting of lancets, absorbent paper, cloth, swabs and cups.

As stated above, Yu et al teach a kit comprising container filled with one or more ingredients of the invention for human administration (column 16, lines 60-63). Yu et al teach a method for the detection of colon cancer or colon cancer metastases comprising the detection of the polynucleotide of Sequence 6 (column 1, lines 3-8). Yu et al also teach and the use of Sequence 6 in genetic testing (column 18, lines 38-65 and column 19, lines 20-32) wherein a sample is taken from the blood of a patients cells..

Feuerstein et al teaches kits comprising polynucleotide probes for the detection of gliomas cells in addition to sampling devices including needles, swabs, aspirators and the like (column 3, lines 55-67).

Quattrocchi teaches test kits for acquiring a human sample which comprise swabs, lancets and gauze pads (page 6, last paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to incorporate Sequence 6 as taught by Yu et al into a kit comprising lancets, swabs and cloth. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Yu et al on genetic testing as a diagnostic for colon cancer and a genetic mutation, and the teachings of Feurerstein e al on the use of kits comprising swabs for the detection of a malignancy.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

May 18, 2003